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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,175	07/14/2005	Peter Von Matt	TX/4-32732A	8299
75/074	75/90	03/31/2008		
NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. 400 TECHNOLOGY SQUARE CAMBRIDGE, MA 02139				
EXAMINER				
KOSACK, JOSEPH R				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
03/31/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/542,175

**Applicant(s)**

VON MATT ET AL.

**Examiner**

Joseph R. Kosack

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-8 and 10-11 are pending in the instant application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 18, 2008 has been entered.

#### ***Previous Claim Rejections - 35 USC § 112***

Claim 11 was previously rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicant's amendments have deleted the non-enabled subject matter, and the rejection is withdrawn.

#### ***Previous Claim Rejections - 35 USC § 103***

Claims 1-8 and 10-11 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al. (WO 02/38561 A1).

Applicant has traversed the rejection on the grounds that it would not have been predictable that the compounds of the present application have therapeutic benefits. This is not found to be persuasive because Albert et al. teach specific examples having bicyclic structures and monocyclic structures in the R position with no apparent loss of activity **for the same utility**. Therefore, it is only a matter of simple substitution for one

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of skill in the art to generate the instant compounds from the compounds of Albert et al.

The rejection is maintained for claims 1-8 and 10-11.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

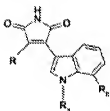
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

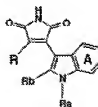
Claims 1-8 and 10-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al. (WO 02/38561 A1).

The instant invention is drawn to compounds of the formula

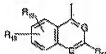


where: R is radical (a); R<sub>1</sub> is piperazine; and all other substituents are as defined. The instant invention is also drawn to its method of preparation and method of use.

Determination of the scope and content of the prior art (MPEP §2141.01)



Albert et al. teach compounds of the formula where: A is optionally substituted, Ra is H or optionally substituted C<sub>1-4</sub> alkyl, Rb is H or C<sub>1-4</sub> alkyl, R

is  where G is CH, E is N, R<sub>11</sub> is a heterocyclic residue, and R<sub>12</sub> and R<sub>13</sub> are optional substitutions. See pages 1-2. Albert et al. teaches specifically piperazine in the R<sub>11</sub> substitution. One example is Example 163 on page 31. Albert et al. teaches the same process of forming the compounds. See page 6. Finally, Albert et al. teaches that the compounds are inhibitors of T lymphocytes and/or PKC. See pages 36-40.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Albert et al. teaches a quinoline (benzofused pyridine) and not teach a pyridine ring in the R position.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Albert et al. teaches other monocycles versus the benzofused cycles with no loss of utility and no apparent loss of activity. Specifically, Albert et al. teaches the R position to be phenyl or naphthelene, and pyrimidine or quinazoline. See page 1.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to follow the synthetic scheme of Albert et al. and pyridine for quinoline to make the claimed invention with a reasonable expectation of success. The motivation to do so is provided by Albert et al. Albert et al. teach the use of the synthesized compounds to treat various diseases mediated by T lymphocytes and/or PKC and the substitution for benzofused rings for the corresponding monocycles. See page 1 and 36-40.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

**Conclusion**

Claims 1-8 and 10-11 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed, Ph.D./  
Primary Examiner, Art Unit 1626

/Joseph R Kosack/  
Examiner, Art Unit 1626